## UNITED STATES DISTRICT COURT DISTRICT OF NEW JERSEY

IN RE: JOHNSON & JOHNSON TALCUM POWDER PRODUCTS MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION

This Document Applies to All Actions Filed Against Defendant Personal Care Products Council MDL No. 16-2738 (FLW) (LHG)

## DEFENDANT PERSONAL CARE PRODUCTS COUNCIL'S STATEMENT OF UNDISPUTED MATERIAL FACTS IN SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT

DATED: May 6, 2019 Respectfully submitted,

PERSONAL CARE PRODUCTS COUNCIL

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- 1. PCPC is a trade association for its members, who are cosmetics and personal care products manufacturers and ingredient suppliers. First Amended Master Complaint ("Compl.")  $\P$  12.
- PCPC is nonprofit corporation organized under the laws of the District of Columbia. PCPC maintains its principal place of business in the District of Columbia.
   Compl. ¶ 11.
- 3. PCPC was formerly known as the Cosmetic, Toiletry and Fragrance Association ("CTFA"). Compl.  $\P$  11.
- 4. PCPC does not and did not mine, process, design, manufacture, market, supply, distribute, sell or otherwise place in the stream of commerce personal care products.

  Compl. ¶¶ 11-12.
- 5. On May 2, 2015, a plaintiff filed a similar bodily injury action, *Denise Celia Simpson*, *et al.* v. *Johnson & Johnson*, *et al.*, case No. 2016 CA 001931 B in the Superior Court of the District of Columbia, against PCPC alleging similar facts and causes of action to the above-captioned matter. *See* Thomas T. Locke's Affidavit (Exhibit A), ¶ 4 (Exh. 1).
- 6. On January 13, 2017, the court dismissed PCPC from *Simpson* because PCPC's acts "were made in furtherance of the right of advocacy on issues of public interest." *See* T.Locke's Aff., ¶ 5 (Exh. 2).
- 7. The U.S. Food and Drug Administration ("FDA") regulates cosmetics. Compl. ¶¶ 40, 53. *See also* 21 C.F.R. §§ 700-740 (2019).
- 8. For example, in 1979, the FDA stated that, based on its independent analysis, "there is no conclusive evidence that pure tale is carcinogenic in man or animals," "most asbestiform minerals also exist in non-fibrous forms," "it is not the chemical nature of asbestos

as much as its physical configuration—long thin fibers—which make it carcinogenic," and "talc and asbestos are not similar in morphology." *See* T.Locke's Aff., ¶ 6 (Exh. 3).

- 9. Similarly, in 2014, the FDA denied two "Citizen's Petitions" seeking warning labels on cosmetic talc products, stating that, "[a]fter careful review and consideration of the information submitted, . . . FDA did not find that the data submitted presented conclusive evidence of a causal association between talc use in the perineal area and ovarian cancer." *See* T.Locke's Aff., ¶ 7 (Exh. 4).
- 10. PCPC published voluntary testing guidelines for its members to determine whether asbestos was in the cosmetic ingredient talc. *See* T.Locke's Aff., ¶ 8 (Exh. 5).
- 11. PCPC did not place its stamp of approval on talc-based body powders. *See* T.Locke's Aff., ¶ 9 (Exh. 6).
- 12. Johnson & Johnson Consumer, Inc. exceeded the PCPC tests by performing additional "gold standard" testing for its talc-based body powders. *See* T.Locke's Aff., ¶ 10 (Exh. 7).
- 13. Information regarding the alleged link between talc-based body powders and ovarian cancer was available to government regulators, scientists and the public. See, e.g., Cosmetic Ingredient Review, <a href="https://www.cir-safety.org">https://www.cir-safety.org</a>, draft reports, information submitted to CIR regarding ingredients, meeting dates and locations, meeting minutes.
- 14. "The current body of experimental and epidemiological evidence is insufficient to establish a causal association between perineal use of talc and ovarian cancer risk." *See*Langseth H, Hankinson SE, Siemiatycki J, Weiderpass E. Perineal use of talc and risk of ovarian cancer. J Epidemiol Community Health 2008; 62:358-360.

- 15. Another Plaintiffs' expert co-authored a study the same year describing the association between perineal talc use and ovarian cancer as "controversial due to the lack of a clear dose-response with increasing frequency or duration of talc use, the possibility of confounding or other biases, and the uncertain biological mechanism." *See* Gates MA, Tworoger SS, Terry KL, Titus-Ernstoff L, Rosner B, De Vivo I, Cramer DW et al. Talc use, variants of the GSTM1, GSTT1, and NAT2 genes, and risk of epithelial ovarian cancer. Cancer Epidemiol Biomarkers Prev 2008; 17:2436-2444.
- 16. In 2007, PCPC's website noted epidemiology studies reporting small increases in ovarian cancer among women who use talc in the perineal area, identified the International Agency for Research on Cancer 2006 analysis, and provided a link to its work. *See* T.Locke's Aff., ¶11 (Exh. 8).
- 17. To this day, most medical and scientific websites do not list perineal use of talc as a risk factor for ovarian cancer. *See, e.g.*, Cancer Council of Australia. Inferred Risk (at: https://www.cancer.org.au/about-cancer/causes-of-cancer/environmental-causes/inferred-risk.html). Sydney: Cancer Council of Australia; 2018; World Cancer Research Fund. Can cosmetics and toiletries cause cancer? (https://www.wcrf.org/informed/articles/can-cosmetics-and-toiletries-cause-cancer). London: World Cancer Research Fund; 2017; CDC. Ovarian Cancer (at: https://www.cdc.gov/cancer /ovarian/ basic\_info/risk\_factors.htm). Atlanta: Centers for Disease Control and Prevention; 2018; American Cancer Society. Ovarian Cancer (at: https://www.cancer.org/cancer/ovarian-cancer/causes-risks-prevention/risk-factors.html). 2019; National Cancer Institute. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention (PDQ) Patient Version (at: https://www.cancer.gov/types/ovarian/patient/ovarian-prevention-pdq#section/\_11). Washington, DC: National Cancer Institute; 2018; Ovacome. Talcum powder

and ovarian cancer: Fact Sheet 14 (at: https://www.ovacome.org.uk/talcum-powder-and-ovarian-cancer). London: Ovacome; 2018; National Cancer Institute. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention—for Health Professionals (PDQ®) (at: https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq#section/\_9). Washington, DC: National Cancer Institute; 2019. *See* T.Locke's Aff., ¶ 12 (Exh. 9).

18. The National Cancer Institute currently states, "The weight of evidence does not support an association between perineal talc exposure and an increased risk of ovarian cancer." See National Cancer Institute. Ovarian, Fallopian Tube, and Primary Peritoneal Cancer Prevention-for Health Professionals (PDQ®) (at: https://www.cancer.gov/types/ovarian/hp/ovarian-prevention-pdq#cit/section\_3.46). Washington, DC: National Cancer Institute; 2018. See T.Locke's Aff., ¶ 13 (Exh. 10).